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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,478	02/25/2002	John L. Ricci	1065.36	4351
7590	04/27/2004		EXAMINER	
Melvin K. Silverman Suite 500 500 Est Cypress Creek Road Fort Lauderdale, FL 33309			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 04/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/081,478	RICCI ET AL.
Examiner	Art Unit	
Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 06 January 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-10 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-10 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 02 May 2002 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

## **DETAILED ACTION**

### ***Election/Restrictions***

1. The Election of Species Requirement is hereby withdrawn.

### ***Priority***

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

It is noted that the present Application is a continuation-in-part of US 6,419,491 B1. The subject matter of a flexible membrane (claim 1), formed of biodegradable material (claims 1 and 6), having a width of between about 200 and about 500 microns (claim 4), having a weight in a range of one to five grams/cm<sup>2</sup> (claim 7), having osteoconductive chemical properties (claims 8 and 9), and having means for suturing into or about a wound or bone defect (claim 10) was not disclosed/described in US 6,419,491 B1. Therefore, the effective filing date is considered to be February 25, 2002.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show "definable center 20" as described in the specification (see page 12, second paragraph). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "means for suturing" (see claim 10, line 2) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Specification*

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

- a. Dimension of upper surface (i.e., "of about 2 to about 10 microns"; see claim 5)
- b. Hench's bioglass, fibrinogen and polyimino-carbonate (see claim 6, line 5)
- c. Weight of reabsorbed material (i.e., "one to five grams/cm<sup>2</sup>"; see claim 7) was not disclosed/described in the specification.

*Claim Objections*

6. Claims 6 and 7 are objected to because of the following informalities:

- a. Regarding claim 6, please (i) delete "as" (see line 2), (ii) add a comma (---) after "polyvinyl alcohols" (see line 4), and (iii) delete "collagen" (see line 5: second occurrence). Appropriate correction is required.
- b. Regarding claim 7, please substitute "resorbed" with --biodegradable--.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5, 6, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 5, the "dimension" renders the claim vague and indefinite as to what exactly is "dimension" referring to. Is it referring to the area occupied by the grooves and ridges, or, the depth and width of each groove and each ridge? This is also not clear from the disclosure. Claims 6, 9, and 10 depend on claim 5.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Curtis et al. (US 5,833,641; cited in Applicants' IDS).

Curtis et al. disclose an article for the healing of wounds and repair of tissue defects (see Abstract) comprising a flexible membrane/sheet (see Figure 1; column 3, line 55 to column 4, line 2) having an upper and a lower surface (see column 5, lines 10-13), each surface defining a substrate formed of a biologically-acceptable biodegradable material adapted to be resorbed in use

(see column 2, lines 31-34; column 3, lines 23-40), each substrate having thereon means capable of orienting cell growth comprising a microgeometry formed in said substrates (see column 4, lines 24-29), a microgeometry of an upper surface proportioned to a cell morphology of soft tissue cells and a microgeometry of a lower surface proportioned to a cell morphology of hard tissue cells (see column 5, lines 10-13; column 2, lines 35-46; column 3, line 55 to column 4, line 2; see entire document). Said membrane/sheet defines a width of between about 200 microns and about 500 microns (see column 3, lines 49-54). Said microgeometries comprise a pattern of grooves and ridges (see Figure 1; column 4, lines 30-67). Each of said microgeometries defining a dimension of about 1 micron to about 10 microns (see column 4, lines 35-44), depending on the targeted cell type (see column 4, lines 35-67).

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Curtis et al. (US 4,832,759), Picha (US 5,002,572), von Recum et al. (US 5,011,494), Athanasiou et al. (US 5,607,474), Naiman et al. (US 5,607,607), Lundgren (US 5,700,479), and Hardwick et al. (US 6,328,765).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the

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organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



April 16, 2004

*Corine McDermott*  
**CORRINE McDERMOTT**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**